Preliminary Statement

This reply memorandum of law is respectfully submitted on behalf of defendant, Richard F. Daines, as Commissioner of the New York State Department of Health ("DOH" or "State defendant") in further support of his motion pursuant to Federal Rule of Civil Procedure 12(c).

POINT I

THE FEDERAL MEDICAID STATUTORY PROVISIONS UPON WHICH PLAINTIFF RELIES DO NOT CREATE AN ENTITLEMENT TO GENDER REASSIGNMENT TREATMENT

Gender Reassignment Treatment is Not Mandated by The Statutes A. **Which Plaintiff Relies Upon**

Contrary to plaintiff's assertion (see Plaintiff's Memorandum in Opposition to Defendant's Motion for Judgment on the Pleadings ("Plaintiff's Opp."), at 1), plaintiff's passing reference to Section 1983 in the opening sentence of the Complaint is not enough to properly establish that plaintiff has a right to relief pursuant to Section 1983. See Complaint, ¶ 1. This is true especially in light of plaintiff's clear indications that her claims and requested relief are allegedly derived from the Medicaid statute directly. See Complaint, Statement of Claims, ¶¶ 63-67 and Wherefore Clause (b)i-iii. However, and in any event, as argued in State Defendant's Memorandum of Law in Support of its Motion for Judgment on the Pleadings ("Defendant's Memo") plaintiff does not have an enforceable right to the care, services, drugs or supplies required for gender reassignment pursuant to Section 1983 or pursuant to any right of action under the Medicaid statute.

- i. 42 U.S.C. 1396a(a)(10)(A) and (B) Do Not Create an Entitlement or a Private Right of Action for the Care Services, Drugs or Supplies for Gender Reassignment Surgery
 - 42 U.S.C. § 1396a(a)(10)(A) requires that a state plan for medical assistance must

provide for making medical assistance available to categorically needy individuals, including at least the care and services listed in 42 U.S.C. § 1396d(a)(1)-(5), (17) and (21), which are simply enumerated as inpatient hospital services, outpatient hospital services, other laboratory and Xray services, physicians services, services furnished by a nurse-midwife and services furnished by a certified pediatric nurse practitioner or certified family nurse practitioner.

Although 42 U.S.C. § 1396a(1)(10)(A) sets forth the broad categories of required medical treatment, there is nothing in the federal Medicaid statute which suggests that a state which chooses to participate in the Medicaid program is required to fund every medical procedure that falls within the delineated categories of medical care. See Beal v Doe, 432 U.S. 438, 441 (1977)(Title XIX does not require states to provide funding for all medical treatment falling within the five general categories). In fact, the Medicaid Act "confers broad discretion on the States to adopt standards for determining the extent of medical assistance" offered in their Medicaid programs. Id. at 444. None of the cases cited by plaintiff supports a determination that this provision provides an enforceable right against State defendant for it to fund a specific medical procedure. See Plaintiff's Opp., at 7-8. Furthermore, gender reassignment treatment is not mentioned among these enumerated services either expressly or by implication.

Meanwhile, 42 U.S.C. § 1396a(a)(10)(B) merely states:

that the medical assistance made available to any individual described in subparagraph (A) - -

- (i) shall not be less in amount, duration, or scope than the medical assistance made available to any other such individual, and
- (ii) shall not be less in amount, duration, or scope than the medical assistance made available to individuals not described in paragraph (A).

42 U.S.C. § 1396a(a)(10)(B). Again, these provisions do not unambiguously confer rights to any

particular and specific service - - let alone to the care, services, drugs or supplies necessary for gender reassignment surgery.

The implementating regulation of 42 U.S.C. § 1396a(a)(10)(B), 42 C.F.R. § 440.230, further illustrates the fact that these provisions are not meant to give plaintiff an enforceable right to a particular benefit. For example, 42 C.F.R. § 440.230 specifies that:

- (a) The [state] plan must specify the amount, duration, and scope of each service that it provides for-
- (1) The categorically needy; and
- (2) Each covered group of medically needy.
- (b) each service must be sufficient in amount, duration, and scope to reasonably achieve its purpose.
- (c) The Medicaid agency may not arbitrarily deny or reduce the amount, duration, or scope of a required service under §§ 440.210 and 440.220 to an otherwise eligible recipient solely because of the diagnosis, type of illness, or condition.
- (d) The agency may place appropriate limits on a service based on such criteria as medical necessity or on utilization control procedures.

42 C.F.R. § 440.230 (emphasis added). Firstly, the indication that the State plan must specify the amount, duration and scope of "each service it provides" implies that the State defendant has discretion on which services it does provide coverage for and therefore is not required to cover every service requested. This is further supported by the regulatory language permitting the State agency to "place appropriate limits on a service based on such criteria as medical necessity or on utilization control procedures." 42 C.F.R. § 440.230(d)(emphasis added). Moreover, interpreting this provision to mean that the State defendant must provide coverage for every possible service which falls within the five broad categories of services is contrary to the fact that the State defendant is entitled to use its discretion and tailor its Medicaid program based on what is "practicable under the conditions in such state." 42 U.S.C. § 1396.

ii. 42 U.S.C. § 1396a(a)(10)(17) Does Not Create an Entitlement to Gender Reassignment Treatment

42 U.S.C. § 1396a(17) provides that:

A State plan for medical assistance must . . . include reasonable standards . . . for determining eligibility for and the extent of medical assistance which . . . are consistent with the objectives of this [Act].

This provision does not manifest a unambiguous intent to confer rights on a particular individual or group. As the ninth Circuit aptly stated in Watson v. Weeks, 436 F.3rd 1152 (9th Cir. 2006): "[t]here is insufficient evidence of congressional intent to create a section 1983 right under this provision. Section 1396a(a)(17) is a general discretion-granting requirement that a state adopt reasonable standards. It fails to provide an "unambiguously conferred right" and fails the first prong of Gonzaga. The key wording of section 1396a(a)(17) fails to even mention individuals or persons. Watson v. Weeks, 436 F.3rd at 1162. Moreover, this section places a focus on the state's standards and their aggregate impact as opposed to the benefits to individuals. Id.; see also Mundell v. Board of County Commissioners of Saguache Count, 2005 U.S.Dist. LEXIS 19815 (Dist. of Colorado 2005) (finding that Congress did not unambiguously create enforceable rights under section 1396a(a)(17); see also Sanders v. Kansas Dep't of Social and Rehabilitation Services, 317 F.Supp.2d 1233, 1250 (Dist. of Kansas 2004)(applying standard set forth in Gonzaga and finding that section 1396a(a)(17) imposes only a duty on the State and creates no rights in individuals and thus does not support a right of action under section 1983).

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Therefore, because 42 U.S.C. § 1396a(a)(17) does not create an unambigously conferred right to any individual, it fails to provide a right, enforceable as an implied right of action or pursuant to 1983, and therefore this claim must be dismissed as against State defendant. See Equal Access for El Paso, Inc. v. Hawkins, 509 F.3rd 697 (5th Cir. 2007)(provision of Medicaid statute which speaks only to the state in their functions of proposing a state plan does not have an individualized focus and is not enforceable under Section 1983).

POINT II

THE STATE REGULATION CONSTITUTES A REASONABLE CONSTRUCTION OF THE FEDERAL MEDICAID STATUTE AND MUST BE AFFORDED SUBSTANTIAL DEFERENCE

Plaintiff's citation to Turner v. Perales, 869 F.2d 140 (2nd Cir. 1988), a case in which there was absolutely no involvement of the federal government, for the proposition that, here, State defendant is not entitled to substantial deference in its interpretation of the federal Medicaid program as afforded by Chevron USA v. Natural Resources Defense Council, Inc., 467 U.S. 837 (1984) ("Chevron") is misplaced (see Plaintiff's Opp., at 10 and 11). Simply put, as already determined by the Second Circuit in Perry v. Dowling, 95 F.3d 231 (2nd Cir. 1996), if the issue is whether the State's construction of the federal Medicaid statute is reasonable it is in fact entitled to substantial deference and the holding in <u>Turner v. Perales</u> is not applicable. <u>See Perry</u> v. Dowling, 95 F.3d at 236. Specifically addressing Turner v. Perales, the Court in Perry v. Dowling reasoned:

> When the federal-statute interpretation is that of a state agency and "no federal agency is involved" deference is not appropriate. Turner v. Perales, 869 F.2d 140, 141 (2nd Cir. 1989)(per curium). Turner does not control the present case, however, for two reasons. First, as we have previously explained, Medicaid is a joint federalstate program that requires, among other things, HHS approval of

state Medicaid plans and their implementation. Thus, here, unlike in *Turner*, a federal agency is involved. Second, the statutory scheme contemplates that once approved by HHS, implementation and operation of Medicaid programs will be conducted by the states."

Perry v. Dowling, 95 F.3rd at 236 (some internal citations omitted).

The Medicaid statute is silent on the issue of coverage for the care, services, drugs or supplies for the purpose of gender reassignment. Therefore, this Court must give substantial deference to DOH's interpretation of the Medicaid statute so long as its interpretation is based on a permissible construction of the statute. See Perry v. Dowling, 95 F.3d at 235-6 citing Cheveron, 467 U.S. at 843; see also Carroll v. DeBuono, 998 F. Supp. 190, 195 (N.D.N.Y. 1998).

Moreover, in an attempt to convince this Court that it must dismiss State Defendant's Motion for a Judgement on the Pleadings, plaintiff makes the unsupported and erroneous assertion that the determination of whether the State's regulation at issue in this matter is consistent with the federal Medicaid Act is fact based. See Plaintiffs Opp., at 12. However, the question of whether state law is consistent with federal law is an issue of law not fact. See Turner v. Perales, 869 F.2d at 141.

For the reasons stated below, as a matter of law, 18 N.Y.C.R.R. § 505.2(1), must be upheld as a valid construction of the federal Medicaid Act and the portions of the Complaint which allege otherwise must be dismissed.

The Validity of 18 N.Y.C.R.R. § 505.2(1) Does Not Hinge Upon the A. Complaint's Allegations as the Regulation Does Not Violate 42 U.S.C. § 1396a(a)(10)(A), 42 U.S.C. 1396a(a)(17) or 42 C.F.R. § 440.210

Although Plaintiff would have this Court find that 42 U.S.C. § 1396a(a)(10)(A) requires

State defendant to fund every medical procedure and/or surgery (including transsexual surgery) that falls within the broad categories of required medical treatment (See Plaintiff's Opp. at 14), this contention ignores the fact that the Medicaid statute uses language which specifically confers broad discretion on the states to adopt standards for determining the extent of medical assistance it must provide by stating that:

> A State plan for medical assistance must . . . include reasonable standards . . . for determining eligibility for and the extent of medical assistance which . . . are consistent with the objectives of this [Act].

42 U.S.C. § 1396a(17); See also Beal v. Doe, 432 U.S. at 444.

Consistent with this requirement to include reasonable standards, as acknowledged by plaintiff (Complaint, ¶ 31), New York Social Services Law ("SSL") provides that medical assistance includes:

> surgical benefits for the certain surgical procedures which meet standards for surgical intervention, as established by the state commissioner of health on the basis of medically indicated risk factors, and medically necessary surgery where delay in surgical intervention would substantially increase the medical risk associated with surgical intervention.

SSL § 365-a(5)(b).

Pursuant to New York State standards Medical assistance also includes:

surgical benefits for other deferrable surgical procedures specified by the state commissioner of health, based on the likelihood that deferral of such procedures for six months or more may jeopardize life or essential function, or cause severe pain; provided, however, such deferrable surgical procedures shall be included in the case of in-patient surgery only when a second written opinion is obtained from a physician, or as otherwise prescribed, in accordance with regulations established by the state commissioner of health, that such surgery should not be deferred.

SSL § 365-a(5)(c).

In any event, plaintiff erroneously claims that the "only" stated reason given by State defendant for its implementation of 18 N.Y.C.R.R. § 505.2(1) is that "treatments for Gender Identify Disorder ("Gender Identity Dysphoria" or "GID") have not been found to be safe and effective." See Plaintiffs Opp., at 13. However, not only is that is simply not the case (See Defendant's Memo., at 19-20) but even if that was the only stated justification such justification would fall squarely within the State defendant's discretion to exclude the surgery.

As indicated in the notice which was published as part of the rule making process before 18 N.Y.C.R.R. § 505.2(1) was promulgated, State defendant found that:

> Consistent with the legislature's objective of providing highquality medical assistance services to MA recipients, the Department [of Health] has the responsibility both of allocating available resources and of assuring that services available to MA recipients are safe and effective. Where as here treatments have not been proven to be safe and effective over the long term, the treatment must be eliminated from the list of available medical assistance services.

Rule Making Activities, NYS Register, July 16, 1997 at 26.

Moreover, there was a comment period before 18 N.Y.C.R.R. § 505.2(1) was promulgated in which comments were accepted and reviewed and the State defendant determined that:

> The department [of health] received comments from two physicians opposing our proposal to deny payment for care, services, drugs or supplies rendered for the purpose of gender reassignment. Both physicians suggested that gender reassignment is an appropriate, effective and safe treatment for persons with gender dysphoria. However, there are equally compelling arguments indicating that gender reassignment, involving ablation of normal organs for which there is no medical necessity because of underlying disease or pathology in the organ, remains an experimental treatment, associated with serious complications. In addition to questions regarding the safety and effectiveness of the surgical procedures themselves, there are serious

questions about the long-term safety of administering testosterone and estrogen at therapeutic levels, required for the remainder of the life of the person who undergoes gender reassignment. Based on these factors, the department intends to move forward with this proposed regulation.

12 N.Y. St. Reg. 5, 8 (1998).1

Certainly, then, contrary to Plaintiff's assertion, State defendant certainly had more than one stated justification for the implementation of 18 N.Y.C.R.R. § 505.2(1) and all justifications are within State's defendant's: 1) ability to include reasonable standards for determining eligibility for and the extent of medical assistance it provides (42 U.S.C. § 1396a(17)); 2) discretion to take into consideration the "conditions of the state" (42 U.S.C. § 1396) when determining the amount and scope of Medical assistance it will provide; and 3) ability to "place appropriate limits on a service based on such criteria as medical necessity or on utilization control procedures." 42 C.F.R. § 440.230(d).

The Plaintiff unpersuasively attempts to convince this Court that just because there may be contrasting medical opinions about the treatment of GID, defendant's motion for judgment on the pleadings must be denied. See Plaintiff's Opp., at 13. However, this is not the case. See

¹ In addition, as reflected in the State Register in 2003 in discussing the continuation of 18 N.Y.C.R.R. § 505.2(1) the State defendant determined that:

[[]The regulation] is consistent with the Legislature's objective of providing high-quality medical assistance services to recipients under the Medicaid program. The Department [of Health] has the responsibility of allocating available resources and assuring that services available are safe and effective. These treatments have not been proven to be safe and effective over the long term, and therefore have been eliminated from the list of covered services under the Medicaid program.

18 N.Y.C.R.R. 505.2(1) Does Not Violate 42 U.S.C. 1396a(a)(17), 42 C.F.R. В. 440.230(c), 440.210 or 440.220

Plaintiff contends that 18 N.Y.C.R.R. § 505.2(1) violates 42 U.S.C. § 1396a(a)(17), 42 U.S.C. § 1396a(a)(10)(B)(i) and their implementing regulation, 42 C.F.R. § 440.230(c), by arbitrarily denying and reducing the amount, duration and scope of a "required service" to plaintiff solely because of her diagnosis, type of illness or condition of Gender Identity Disorder ("GID"). Complaint, ¶ 65; Plaintiff's Opp., at Plaintiff's Opp., at 16. This argument also fails.

² Interestingly, the cited Harry Benjamin International Gender Dysphoria Association's Standards of Care for Gender Identity Disorders, (6th Version 2001) (Plaintiff's Opp., at 13, Complaint, ¶ 39), acknowledges that "all readers [of the Standards of Care for Gender Identity Disorders] should be aware of the limitations of knowledge in this area and of the hope that some of the clinical uncertainties will be resolved in the future through scientific investigation." Id., at 1.

First, plaintiff omits the key text of 42 C.F.R. § 440.230, which states that:

- (a) The [state] plan must specify the amount, duration, and scope of each service that it provides for-
- (1) The categorically needy; and
- (2) Each covered group of medically needy.
- (b) each service must be sufficient in amount, duration, and scope to reasonably achieve its purpose.
- (c) The Medicaid agency may not arbitrarily deny or reduce the amount, duration, or scope of a required service under §§ 440.210 and 440.220 to an otherwise eligible recipient solely because of the diagnosis, type of illness, or condition.
- (d) The agency may place appropriate limits on a service based on such criteria as medical necessity or on utilization control procedures.

42 C.F.R. § 440.230 (emphasis added).

In order for plaintiff to prevail on this claim the Court must incorrectly assume first, that the care, services, drugs, or supplies which are needed for the purpose of gender reassignment is a required service under 42 C.F.R. §§ 440.210 and 440.220 and that the State defendant has arbitrarily denied it based solely on diagnosis of GID. Id. In addition, the Court would have to ignore the fact that the State defendant is entitled to place appropriate limits on the services it does provide. Id.

Not only are the care, services, drugs, or supplies which are needed for the purpose of gender reassignment not a required service, even assuming they were, plaintiff fails to establish that State defendant arbitrarily excludes such care, services, drugs, or supplies only for those individuals with GID and because those individuals have GID. The exclusion of coverage is not based upon the diagnosis of GID. See 12 N.Y. St. Reg. 5, 8 (1998). However, even if this Court agrees with plaintiff and assumes that the exclusion is based solely on the diagnosis of GID, this exclusion is certainly not arbitrary but is instead because of a determination by State defendant

that:

gender reassignment, involving ablation of normal organs for which there is no medical necessity because of underlying disease or pathology in the organ, remains an experimental treatment, associated with serious complications. In addition to questions regarding the safety and effectiveness of the surgical procedures themselves, there are serious questions about the long-term safety of administering testosterone and estrogen at therapeutic levels, required for the remainder of the life of the person who undergoes gender reassignment.

12 N.Y. St. Reg. 5, 8 (1998).

Therefore, plaintiff has failed to establish that the promulgation and implementation of 18 N.Y.C.R.R. § 505.2(1) violates 42 U.S.C. § 1396a(a)(17), 42 U.S.C. § 1396a(a)(10(B)(i) and 42 C.F.R. § 440.230(c).

C. 18 N.Y.C.R.R. § 505.2(1) Does Not Violate 42 U.S.C. § 1396a(a)(10)(B)(i) or 42 C.F.R. § 440.240(b)

Plaintiff claims that 18 N.Y.C.R.R. § 505.2(1) also violates 42 U.S.C. § 1396a(10)(B)(i) and its implementing regulation, 42 C.F.R. § 440.240(b). See Complaint, ¶ 64; Plaintiff's Opp., at 16. However, for the following reasons plaintiff's argument again fails.

The purpose of 42 U.S.C. § 1396a(a)(10)(B) and 42 C.F.R. § 240(b) is to guarantee that if a state elects to provide medical assistance to the medically needy, it must also provide it to the categorically needy and it may not provide more assistance to the former group than to the latter. Rodriguez v. City of New York, 197 F.3d 611, 615 (2nd Cir. 1999); see also Schweiker v. Hogan, 457 U.S. 569, 573 n.6 [] (1982); see also Sobky v. Smoley, 855 F.Supp. 1123, 1140 (E.D. Cal. 1994).

Therefore, even accepting all of plaintiff's arguments as true and assuming for argument's sake that vaginoplasty and orchietomy surgery (which the State does proved coverage for in some limited circumstances (see Complaint, ¶ 32 and Plaintiff's Opp., at 16) is the same exact service as the care, services, drugs or supplies needed for the purposes of gender reassignment (a point which State defendant does not concede). State defendant acted well within its discretion in considering the medically indicated risk factors associated with such surgery when used for the treatment of GID as opposed for other conditions. See SSL § 365a(5)(b) and (c), relevant text cited in full in Point II(A), supra; See also 12 NY St. Reg. 5, 8 (1998), relevant text cited in full in Point II(B), supra. Therefore, contrary to plaintiff's assertions (see Plaintiff's Opp., at 16), even if the Court finds that a distinction is made solely because of diagnosis of GID, the rationale behind the distinction is not arbitrary and therefore does not violate 42 C.F.R. § 440.230(c).

Therefore, because State defendant's decision to implement 18 N.Y.C.R.R. § 505.2(1) does not impermissibly discriminate under 1396a(a)(10)(B) and because State defendant's determination to exclude the care, services, drugs or supplies for the purpose of gender reassignment was reasonable, plaintiff fails to establish a claim against State defendant pursuant to these sections of the federal Medicaid law.

POINT III

18 N.Y.C.R.R. § 505.2(1) DOES NOT VIOLATE THE EQUAL PROTECTION CLAUSE OF THE FOURTEENTH AMENDMENT

Plaintiff contends that State defendant is violating her rights under the equal protection clause of the Fourteenth Amendment to the United States Constitution by "denying care, services, drugs and/or supplies to Plaintiff to treat her GID while providing the same care, services drugs and/or supplies to categorically needy Medicaid recipients suffering from illness other than GID with no rational basis." Complaint, ¶ 66; Plaintiff's Opp. at 18. This contention is unsupported and without merit and must be dismissed.

The State defendant need only have a rational basis for its decision to provide Medicaid benefits in some instances but not in others. See Schweiker v. Hogan, 457 U.S. 569 (1982); see also Dandridge v. Williams, 397 U.S. 471, 485 (1970). "On a rational basis review, a classification [bears] a strong presumption of validity, and those attacking the rationality of the legislative classification have the burden to 'negative every conceivable basis which might support it." Hines v. Sheehan, 1995 U.S.Dist. LEXIS 11031 (Dist. of Maine 1995) citing Federal Communications Comm'n v. Beach Communications, Inc., 113 S.Ct. 2096, 2102 (1993).

State defendant continues to maintain that 18 N.Y.C.R.R. 505.2(1) does not draw a distinction between those who suffer from GID and those that do not. However, even if this Court finds that it does draw such a distinction. State defendant certainly has a rational basis to do so. For example, State defendant certainly has a rational basis to draw the distinction between the ablation of healthy organs for which there is no medical necessity because of underlying disease or pathology and organs which do suffer from disease or pathology. See 12 N.Y. St. Reg. 5, 8 (1998). In addition, the State defendant has concerns about the long-term safety of administrating testosterone and estrogen at the rapeutic levels for the remainder of the life of the person who undergoes gender reassignment. Id.

Therefore, State defendant has not violated plaintiff's rights under the equal protection clause of the 14th Amendment. See Hines v. Sheehan, 1995 U.S. Dist. LEXIS 11021 (finding that under the extremely deferential standard of review the Equal Protection Clause does not forbid the state from choosing one disease at the expense of others and that if lines must be drawn disease diagnosis is a rational way to differentiate and in the social welfare area there appears to

be no requirement that the state justify its choice); <u>See Rush v. Johnson</u>, 565 F.Supp. 856, 868-869 (N.D. Georgia 1983)(State's prohibition against reimbursement for transsexual surgery was rational and did not violate the equal protection clause); <u>see also G.B. Lackner</u>, 80 Cal.App.3rd 64, 86 (1978)(finding that the state's refusal to finance transsexual surgery which includes surgical removal and reconstruction of organs which are not diseased, damaged or deformed even though it does so in other circumstances when the organs are diseased, damaged or deformed does not violate the equal protection clause).

CONCLUSION

For the reason set forth above, the Court should grant State defendant's motion for judgment on the pleadings and grant such other and further relief as the Court deems just and proper.

Dated: New York, New York January 31, 2008

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